Dasatinib (drug) treats leukemia in adults and pediatrics. Out of 6 studies that both adult and pediatric populations were eligible for, only 1 study included pediatrics. For this study, it is unclear how many pediatric participants constitute the 88.9% of "pediatric representation" since the data grouped pediatrics and adults together as 1 category: ages 15-64 years old. Data presentation influences how studies are understood, thereby affecting the development of dosage and labeling information.

**Who is the Pediatric Population?**

Individuals aged 0 to <17 years

**Why Include the Pediatric Population?**

- In 2014, Children's Hospital Los Angeles had **15,145** in-patient visits and an estimated **26,503** out-patient visits who could have benefited from access to clinical trials.
- The Centers for Disease Control and Prevention (CDC) reports ~**200,000** children visit ERs annually due adverse drug effects, and for most visits involving medication errors, young children are given the wrong dose of medicine.
- Our research shows that although the pediatric population can participate in pediatric and adult eligible studies, this does not necessarily equate to sufficient numbers of pediatric subjects recruited and retained in clinical trials.

### Example of the Analysis of a Drug Approved under BPCA

<table>
<thead>
<tr>
<th>Study Title</th>
<th>% Pediatric Subjects</th>
<th>% Pediatric Subjects (combined categories)</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dasatinib and Combination Chemotherapy in Treating Young Patients with Newly Diagnosed Acute Lymphoblastic Leukemia</td>
<td>----</td>
<td>88.9%</td>
<td>Could not determine specific number of pediatric participants from data presented.</td>
</tr>
<tr>
<td>Dasatinib and Erlotinib in Non-Small Cell Lung Cancer (NSCLC)</td>
<td>0%</td>
<td>----</td>
<td>Eligible for Study: 16 Years and Older</td>
</tr>
<tr>
<td>Trial of Dasatinib in Advanced Sarcomas</td>
<td>0%</td>
<td>----</td>
<td>Eligible for Study: 13 Years and Older</td>
</tr>
<tr>
<td>Therapy of Chronic Lymphocytic Leukemia with Dasatinib (BMS-354825)</td>
<td>0%</td>
<td>----</td>
<td>Eligible for Study: Child, Adult, Older Adult (No numerical specification)</td>
</tr>
<tr>
<td>Interleukin 11, Thrombocytopenia, Iatrogenic in Chronic Myelogenous Leukemia (CML) Patients</td>
<td>0%</td>
<td>% Peds of Subjects (combined categories)</td>
<td>Eligible for Study: Child, Adult, Older Adult (No numerical specification)</td>
</tr>
</tbody>
</table>

- Dasatinib (drug) treats leukemia in adults and pediatrics.
- Out of 6 studies that both adult and pediatric populations were eligible for, only 1 study included pediatrics.
- For this study, it is unclear how many pediatric participants constitute the 88.9% of "pediatric representation" since the data grouped pediatrics and adults together as 1 category: ages 15-64 years old.
- Data presentation influences how studies are understood, thereby affecting the development of dosage and labeling information.

**Contact Information**

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**Examination of FDA Pediatric Regulations: Inclusion of Pediatric Participants in Clinical Trials**

Annie Ly, MS Candidate; Apurva Uniyal, MA, MS; Yu Chung, MPH, MS; Terry Church, DRSc

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**Physiological Difficulties**

i.e. route of administration

**Ethics**

i.e. risk vs. benefit

**Economics**

i.e. manufacturer incentives

**Pharmacometric Challenges**

i.e. child growth